

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier G. Kenley

[Docket No. 01D-0475]

**Guidance for Industry on Providing Regulatory Submissions in Electronic Format—
ANDAs; Availability**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Providing Regulatory Submissions in Electronic Format—ANDAs." This guidance provides information for applicants on how to submit abbreviated new drug applications (ANDAs) in electronic format.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Ruth A. Warzala, Center for Drug Evaluation and Research (HFD-600), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-5845, e-mail: ESUB__OGD@CDER.fda.gov.

SUPPLEMENTARY INFORMATION:

cd0248

NAD-2

I. Background

FDA is announcing the availability of a guidance for industry entitled "Providing Regulatory Submissions in Electronic Format—ANDAs." Traditionally, FDA has required that regulatory submissions, such as ANDAs and new drug applications, be submitted as paper documents. In the **Federal Register** of March 20, 1997 (62 FR 13430), FDA published the electronic records and electronic signatures regulation, which provided for the voluntary submission of parts or all of an application, as defined in the relevant regulations, in electronic format without an accompanying paper copy (21 CFR part 11). The agency also established public Docket No. 92S-0251 to provide a list of the agency units that are prepared to receive electronic submissions and the specific types of records and submissions that can be accepted in electronic format (62 FR 13430 at 13467). In the Prescription Drug User Fee Act as amended by the Food and Drug Administration Modernization Act of 1997 (Public Law 105-115), the agency stated its plans to develop and update its information management capabilities to allow electronic submissions by 2002. In the **Federal Register** of January 28, 1999, the agency announced the availability of two guidances for industry entitled "Providing Regulatory Submissions in Electronic Format—NDAs" (64 FR 4432) and "Providing Regulatory Submissions in Electronic Format—General Considerations" (64 FR 4433). These guidances were the first two of a series of guidances for industry on making regulatory submissions in electronic format. This guidance should be used in conjunction with "Providing Regulatory Submissions in Electronic Format—NDAs" and "Providing Regulatory Submissions in Electronic Format—General Considerations."

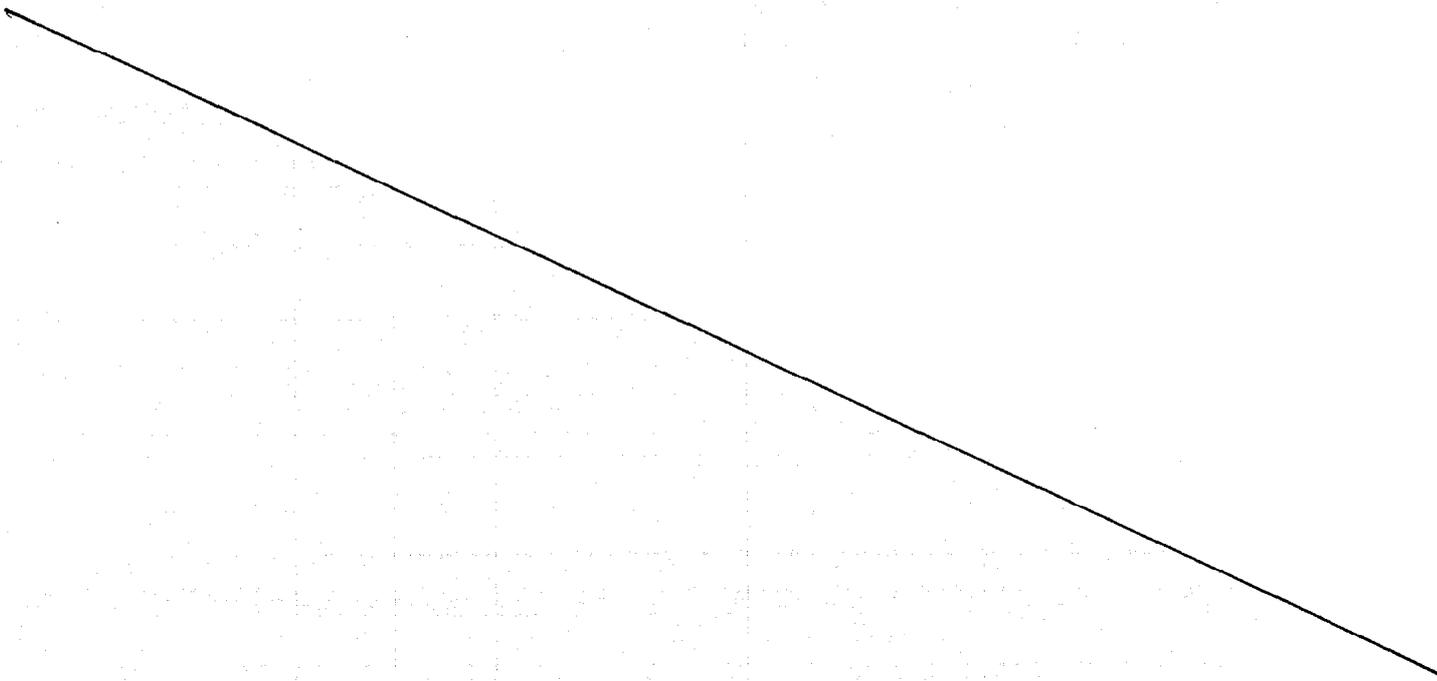
The Center for Drug Evaluation and Research (CDER) has encouraged the electronic submission of some types of data on a voluntary basis since 1997. However, these electronic submissions could not previously be archived and could only be made in addition to a complete paper submission. In the **Federal Register** of November 16, 2001 (66 FR 57721), CDER announced the availability of a draft guidance entitled "Providing Regulatory Submissions in Electronic Format—ANDAs." This guidance provided new information on submitting a complete

archival copy of the ANDA in electronic format. The comment period closed on January 15, 2002, and the agency considered the received comments as it finalized this guidance. As in the past, applicants planning to make submissions in electronic format should consult public Docket No. 92S-0251 to determine which agency units are prepared to receive electronic submissions and the specific types of documents that can be submitted in electronic format.

This guidance is being issued consistent with FDA's good guidance practices (GGPs) regulation (21 CFR 10.115). The guidance represents the agency's current thinking on providing regulatory submissions in electronic format for ANDAs. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes or regulations.

II. Comments

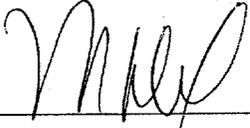
Interested persons may, at any time, submit written or electronic comments on the guidance to the Dockets Management Branch (see **ADDRESSES**). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.



III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: 6/11/02
June 11, 2002.



Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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Gloria Bentley